

APPENDIX D: REQUEST FOR HUMAN SUBJECTS EXEMPTION FOR ATP PROPOSALS -- INFORMATION TECHNOLOGY, DATA, MANUFACTURING, AND IMAGING STUDIES

The following information must be supplied along with the proposal to allow for NIST/ATP to have an independent evaluation performed of a possible exemption from 15 CFR Part 27, Protection of Human Subjects. **Proposers are reminded that the term data includes collection of data from voice, video, digital or image recordings made for research purposes.**

1. What is the timeframe (start and end dates) for human subject/data/image involvement?
2. State the technical justification for human subject/data/image involvement (i.e. No other way to achieve equivalent technical outcome? Why?).
3. Are the data/images stripped of any identifiable information (e.g. personal identifiers such as names or codes which can be traced back to the human donor or source)? Explain.
4. Are the data/images publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate. **NOTE:** An answer of “no” to either question #3 or #4 may disqualify the project from an exemption. In those cases, an appropriate IRB approval may be required, and should accompany the proposal if the work is within the first year of the project.
5. Are the data/images/recording pre-existing, being collected for the express purpose of the research, or obtained by some combination of the two?
6. What is the source of the data/image/recording (e.g. video archives, proprietary database, security systems/records, medical records, video conference records, etc.)?
7. What is the extent of data/image/recording handling by the Principal Investigator: collecting, receiving, and/or sending data/images?
8. What is the extent of contact by the Principal Investigator with human subjects: personal observation, image recording, survey questions, etc.?
9. What is the extent of control by the Principal Investigator of the environment in which the human subject will be monitored?
10. Do the data/images/recording come from individuals who may need special safeguards (i.e. minor children, pregnant women, human in vitro fertilization, fetuses, or prisoners)? **NOTE:** An answer of “yes” to question #10 disqualifies the project from exemption under 15 CFR Part 27. In these cases, the proposal protocol/task descriptions **MUST** be reviewed and approved by an IRB that possesses a current assurance, appropriate for the research in question, on file with the Office of Protection from Research Risks (OPRR) of the Department of Health and Human Services, and which has been approved by OPRR for federalwide use. This IRB approval **MUST** accompany the proposal at submission.
11. Is the image/recording being recorded in fact “public behavior”? Some indicators of public behavior would be:
 - a) image of behavior does NOT give rise to any cause of action under ANY legal theory protecting personal privacy;
 - b) there are NO trade secrets or OTHER CONFIDENTIAL INFORMATION of any person contained in the image or recording;
 - c) there are NO copyright restrictions OR, the copyright holder has granted written permission to the proposer;

d) any other matter the proposer deems germane to this issue.

12. If answer to #11 is “yes”:

- a) can the human subjects be identified directly or through identifiers?
- b) if the human subjects can be identified, any disclosure would NOT reasonably place the subjects at risk of criminal or civil liability, standing, employability or reputation.

13. Has the research been reviewed by an IRB? If yes, attach a copy of the review.

The following signed statement must accompany the answers to the above questions:

This is an accurate description of the proposed research involving human subjects/tissues. Any changes in protocol or task descriptions will be submitted in advance to the IRB as appropriate, and to ATP prior to notification of ATP award decisions.

Signature, Principal Investigator

Date